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| APPLICATION NO.            | FILING DATE                       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |  |
|----------------------------|-----------------------------------|----------------------|---------------------|------------------|--|--|
| 10/573,730                 | 03/28/2006                        | Vladimir Pekar       | PHUS030326US        | 2262             |  |  |
|                            | 7590 12/24/200<br>LLECTUAL PROPER | EXAMINER             |                     |                  |  |  |
| P. O. Box 3001             |                                   | HARRIS, CARRIE R     |                     |                  |  |  |
| BRIARCLIFF MANOR, NY 10510 |                                   |                      | ART UNIT            | PAPER NUMBER     |  |  |
|                            |                                   |                      | 3735                |                  |  |  |
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|                            |                                   |                      | 12/24/2009          | PAPER            |  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Application No.           |                                                             | Applicant(s)        |              |  |  |  |
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| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 10/573,730                |                                                             | PEKAR ET AL.        |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Examiner                  |                                                             | Art Unit            |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Carrie Harris             |                                                             | 3735                |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                           |                                                             |                     |              |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |                                                             |                     |              |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |                                                             |                     |              |  |  |  |
| 1) 又                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Responsive to communication(s) filed on 19 Au                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | iaust 2009                |                                                             |                     |              |  |  |  |
| •                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Responsive to communication(s) filed on <u>19 August 2009</u> .  This action is <b>FINAL</b> . 2b) ☐ This action is non-final.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                           |                                                             |                     |              |  |  |  |
| 3)□                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <i>,</i> —                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |                                                             |                     |              |  |  |  |
| J)الــا                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                           |                                                             |                     |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | closed in accordance with the practice under Ex pane Quayle, 1935 C.D. 11, 455 C.G. 213.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                           |                                                             |                     |              |  |  |  |
| Dispositi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | on of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                           |                                                             |                     |              |  |  |  |
| 4)🛛                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ☑ Claim(s) <u>1-7 and 9-17</u> is/are pending in the application.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                           |                                                             |                     |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 4a) Of the above claim(s) is/are withdrawn from consideration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                           |                                                             |                     |              |  |  |  |
| 5)🛛                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ☐ Claim(s) <u>9-11 and 13</u> is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                           |                                                             |                     |              |  |  |  |
| ·                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ☑ Claim(s) <u>1 and 14</u> is/are rejected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                           |                                                             |                     |              |  |  |  |
| · —                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Claim(s) <u>2-7,12 and 15-17</u> is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                           |                                                             |                     |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Claim(s) are subject to restriction and/or                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | election requiremen       | ıt.                                                         |                     |              |  |  |  |
| ٥,١                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | and conspect to recommend and are seen are seen as a seen are seen are seen as a seen are seen a |                           |                                                             |                     |              |  |  |  |
| Applicati                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | on Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                           |                                                             |                     |              |  |  |  |
| 9)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | The specification is objected to by the Examine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | •.                        |                                                             |                     |              |  |  |  |
| 10)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | The drawing(s) filed on is/are: a)  acc∈                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | epted or b)⊟ objecte      | ed to by the E                                              | xaminer.            |              |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |                                                             |                     |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Replacement drawing sheet(s) including the correcti                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | on is required if the dra | awing(s) is obj                                             | ected to. See 37 CI | FR 1.121(d). |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |                                                             |                     |              |  |  |  |
| Priority ι                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | ınder 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                           |                                                             |                     |              |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |                                                             |                     |              |  |  |  |
| 2)  Notic<br>3) Infori                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | e of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Pape<br>5) Notice         | view Summary<br>er No(s)/Mail Da<br>ce of Informal Pa<br>r: |                     |              |  |  |  |

# **DETAILED ACTION**

1. This Office action is responsive to the Amendment filed 19 August 2009. The Examiner acknowledges the amendments to claims 1, 7, 9, 11, and 14-16, the cancellation of claim 8, as well as the addition of claim 17.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35
 U.S.C. 102 that form the basis for the rejections under this section made in this
 Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Di Yan et al., "A Model or Accumulate Fractionated Dose in a Deforming Organ". International Journal of Radiation Oncology, Biology, Physics 44.3 (1999): 665-675.

Regarding **claim 1**, Di Yan et al. teaches a method of planning a radiation therapy, the method comprising the steps of: determining a dose distribution for a target volume on the basis of a first image (CT image obtained prior to treatment for planning, p. 666, col. 2, paragraphs 1 and 2; p. 669, col. 1, paragraph 3); determining at least one of shape and position variation of a surface of an object of interest in the target volume between the first image and a second image (reference image is the planning CT image, and organ motion at each treatment

Art Unit: 3735

Application/Control Number: 10/573,730

fraction is calculated with respect to the original planning position, page 666, column 2, paragraphs 1 and 2; Shape and position variation of a surface of an organ is necessarily incorporated with a study of the shape and position variation of the organ as a whole.); and adjusting the dose distribution on the basis of the at least one of shape and position variation (total dose, D(v), depends on the calculated organ displacement, p. 669, col. 1, paragraph 1); and storing the adjusted dose distribution and displaying the adjusted dose distribution (daily dose-volume histograms for the organ of interest are plotted, p. 671, col. 2; p. 672, col. 1, paragraph 1); wherein the first and second images where taken at different points in time of a radiation treatment process (planning CT image is a first image, and image at a fraction treatment is a second image taken at different points in time, p. 666, col. 2, paragraph 1).

Regarding **claim 14**, Di Yan et al. teaches a method for adapting a dose distribution of a radiation therapy plan comprising: adapting a first surface mesh to an object of interest in a first image resulting in a first adapted surface mesh (reference image, p. 667, col. 1, paragraph 1); adapting a second surface mesh to the object of interest in a subsequent image resulting in a second adapted surface mesh (second image is k treatment CT image that is analyzed with the same volumetric mesh procedure as the first image, p. 668, col. 2, paragraph 1); deforming a volumetric model of the object of interest based on a difference between the first adapted and second adapted surface meshes (calculates displacement and new position of the organ based on a subsequent image, which is volumetric organ deformation, p. 668, col. 1, paragraph 3); and storing

Art Unit: 3735

the deformed volumetric model and displaying the deformed volumetric model (see *Figures 3, 4, and 6*).

# Response to Arguments

4. Applicant's arguments filed 19 August 2009 with respect to the rejection of claims 1 and 14 under 35 U.S.C. 102(b) citing Di Yan have been fully considered but they are not persuasive. Applicant contends that Di Yan does not teach determining at least one of shape and position variation of a surface of an object of interest in the target volume between the first image surface mesh and second image surface mesh and adjusting the dose distribution on the basis of the at least one of shape and position. The Examiner does not find this argument persuasive because Di Yan teaches applying a volumetric mesh to a first and subsequent images, then determining the shape and position variation of a surface of an object of interest in the target volume based on the displacement between the first and second volumetric meshes, as illustrated in Figures 3, 4, and 6. The volumetric meshes necessarily incorporate the partitioning of the organ surface as they are used to study and model the deformation of the entire organ, see Figure 6. Di Yan teaches that the dose distribution applied to the tissue is adjusted based on each new set of image data during the radiation treatment process, see Figure 7 and page 672, col. 1, paragraph 1. Therefore, the previous grounds of rejection of claims 1 and 14 have been maintained.

Application/Control Number: 10/573,730 Page 5

Art Unit: 3735

5. Applicant's arguments, see pages 9-10, filed 19 August 2009, with respect to claims 2, 9, and 10 have been fully considered and are persuasive. The rejection of claims 2-7, 9-13, 15, and 16 have been withdrawn.

#### Allowable Subject Matter

- 6. Claims 2-7, 12, and 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 7. Claims 9-11 and 13 are allowed.
- 8. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teach or fairly suggest a method of planning a radiation therapy comprising the steps of applying a first surface mesh to the object of interest in a first image, performing an adaptation of the first surface mesh to a surface of the object of interest in a target volume in the first image resulting in a second surface mesh, applying the same second surface mesh to the object of interest in a second subsequently captured image, performing a second adaptation of the second surface mesh to the surface of an object of interest in the second image resulting in a third surface mesh, determining the deformation of the object of interest between the first and second images based on the difference between the second and third surface meshes, determining and adjusting the radiation dose distribution in the target volume based on the determined deformation.

Application/Control Number: 10/573,730 Page 6

Art Unit: 3735

#### Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Harris whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/573,730 Page 7

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/ Supervisory Patent Examiner Art Unit 3735

/C. H./ Examiner, Art Unit 3735